REMARKS/ARGUMENTS

Claims 1, 2 and 4-15 have been amended and claim 3 has been cancelled. Claim 1 has been amended to incorporate the limitation of cancelled claim 3 that the peptide component is from 8 to 500 amino acid residues long, and also to specify that the peptide component is covalently bonded at the amino and/or carboxy terminus thereof to at least one lipophilic substituent. Support for the limitation relating to covalent bonding may be found in the specification on page 7, line 15. In addition, claims 2 and 4-15 have been amended for clarity to change the phrase "A particle according to claim 1" to "The particle according to claim 1." Accordingly, no new matter has been added by way of amendment or the addition of claims.

Claims 1, 2 and 4-15 are pending in the application. Reexamination and reconsideration of the claims are respectfully requested in view of the claim amendments and the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Objections to the Claims Should Be Withdrawn

Claims 3-6 and 15 have been objected to for informalities relating to dependencies from rejected base claims and for the recitation of "A particle according to claim 1." Claim 3 has been cancelled, claims 2 and 4-15 have been amended to recite "The particle according to claim 1", and claim 1 has been amended to overcome the Examiner's rejection, as described more fully below. Accordingly, these objections have been obviated.

The Rejection of the Claims Under 35 U.S.C. §102 (b) Should Be Withdrawn

Claims 1, 2, and 7-14 are rejected under 35 U.S.C. §102(b) as being anticipated by Lundberg *et al.* (1993) *Biochim. Biophys. Acta* 1149:305-12. This rejection is respectfully traversed.

The Examiner contends that Lundberg *et al.* teach a non-naturally occurring receptor competent LDL particle comprising a peptide component (apolipoprotein B) wherein the peptide component has a binding site for an Apo B protein receptor and a lipophilic substituent that contains cholesterol. The Examiner further states that the presence of hydroxyl, carboxyl, and

amino groups is inherent in the amino acids that make up peptides. Finally, the Examiner states that since the peptide component of the particle is apolipoprotein B, it is inherent that the peptide has 100% amino acid identity to an Apo B protein binding sequence. For these reasons, the Examiner states that the limitations of claims 1, 2, and 7-14 have been met.

Although for the reasons of record Applicants disagree with the view of the Examiner that Lundberg *et al.* teaches an LDL particle falling within the scope of claim 1, solely in the interest of expediting prosecution, Applicants have amended claim 1 to incorporate the limitation that the peptide component is from 8 to 500 amino acid residues long and is covalently bonded at the amino and/or carboxy terminus thereof to at least one lipophilic substituent. For the reasons provided below, Applicants submit that these amendments further distinguish claim 1 from the Lundberg *et al.* reference.

First, Lundberg *et al.* fail to teach covalent bonding of the peptide-lipophilic substituent as recited in currently amended claim 1. The Examiner considers Lundberg *et al.* to teach an LDL particle wherein the amino and carboxy terminus is inherently bonded via ionic bonding to a lipophilic substituent due to its charged nature. The procedure described in Lundberg *et al.* for joining apolipoprotein B with liposomes is detailed at page 306, right hand column. A mixture of two lipid components in the preparation of the apoB-liposome conjugates is used. The first lipid component is POPC (palmitoyloleoylphosphatidylcholine), which is positively charged. If ionic bonding was to take place, such would only be possible with the carboxy terminus of the peptide component as this end of the peptide can become negatively charged. An ionic bond in these circumstances is weaker than a covalent bond and is therefore easily disrupted and broken. The second lipid component described by Lundberg is cholesterol, and this is not ionized under physiological conditions and therefore cannot form any ionic bonds with the peptide component. Although it may be possible that the cholesterol component may undergo hydrogen bonding to the peptide component, hydrogen bonding is much weaker than ionic and covalent bonds and is therefore easily disrupted. Therefore, even if such a bond/association between the lipid component and peptide component in the Lundberg *et al.* conjugates does exist, the association between the lipid component and the protein would be an easily disrupted physical attraction, rather than a strong peptide-lipophilic substituent <u>covalent bond</u> as in currently amended claim 1.

Second, Lundberg *et al.* fails to teach the use of a shorter amino acid residue peptide (rather than the whole Apo B protein) covalently bonded to lipophilic substituents as recited in currently amended claim 1. Covalent bonding enables the lipophilic substitutents to be securely tethered to the peptide component as an anchor, which enables a shorter sequence of 8 to 500 amino acid residues peptide to be used instead of the whole Apo B protein. Thus, the present invention ensures the successful formation of non-naturally lipoprotein particles through the use of a shorter amino acid residue peptide rather than the whole Apo B protein while retaining ApoB receptor competency.

Because the Lundberg *et al.* reference does not disclose a peptide component that is from 8 to 500 amino acid residues long and that is covalently bonded at the amino and/or carboxy terminus thereof to at least one lipophilic substituent, this cited reference does not meet all of the limitations of currently amended claim 1 (and therefore, claims 2 and 7-14 which depend from and incorporate the limitations of claim 1). To anticipate a claim, a reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Accordingly, Applicants respectfully request that the rejection of claims 1, 2, and 7-14 under 35 U.S.C. §102(b) be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the objections to the claims have been obviated, and that the rejection of the claims under 35 U.S.C. §102(b) is overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required. However, in the event that extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 C.F.R. §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 23, 2006

Lynda-Jo Pixley